

U.S.S.N. 09/706,045
Filed: November 3, 2000
AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Claims 23-39 are pending. Claims 23, 24, 27, 28, and 32 have been amended. Claim 23 was amended to replace "and/or" with "or". Claim 23, as amended, encompasses the same subject matter as it did prior to this amendment. As defined by amended claim 23, (1) the porous matrix may have a TAP density that is less than or equal to 1.0 g/mL and a total surface area of greater than or equal to 0.2 m²/g, or (2) the porous matrix may have a TAP density that is less than or equal to 1.0 g/mL or a total surface area of greater than or equal to 0.2 m²/g. Claims 24, 27, 28, and 32 have been amended to delete "suitable for administration by" and substitute it with "administered by". Applicants believe that it is proper for the present amendment to be entered since it does not add any new matter, raise any new issues, and does not require further consideration or search.

Rejection Under 35 U.S.S.N. § 102

Claims 23-39 were rejected under 35 U.S.S.N. § 102(b) as being anticipated by U.S. Patent No. 6,565,885 to Tarara et al ("Tarara"). Applicants respectfully traverse this rejection.

35 U.S.C. § 102(b)

Tarara is not available as prior art under 35 U.S.C. § 102(b). 35 U.S.C. § 102(b) applies to references that were published more than one year before the priority date of the application they are cited against. Tarara issued as a patent on May 20, 2003. The present application was filed on November 3, 2000 and claims priority to an application filed on May 27, 1999. Thus

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Tarara was clearly published after the priority date of the present application. Therefore the rejection of claims 23-39 under 35 U.S.C. § 102(b) is improper.

Tarara's earliest priority date for the relevant disclosure is September 29, 1998

For the disclosure of including a volatile salt in the feed stock to the spray dryer, the earliest date that Tarara is entitled to claim priority to is September 29, 1998, the filing date of PCT/US98/20602. The first three applications to which Tarara claims priority, do not disclose using volatile salts as the blowing or inflating agent. For example, U.S.S.N. 60/060,337, filed September 29, 1997 states that suitable inflating agents include low-boiling solvents (below 100°C) with limited miscibility in aqueous solutions (e.g. methylene chloride, acetone and carbon disulfide), a gas (e.g. CO₂ or N₂) which saturates the solution at room temperature and elevated pressure (e.g. 3 bar), and emulsions of immiscible low-boiling liquids (e.g. Freon 113, perfluoropentane, perfluorohexane, perfluorobutane, pentane, butane, FC-11, etc.) (page 29, lines 1-11 and page 31, line 31 until page 32, line 15). U.S.S.N. 09/106,932 and U.S.S.N. 09/133,848 contain similar disclosures.

WO 99/16419, filed as PCT/US98/20602 on September 29, 1998, is the first priority application that lists a volatile salt as a suitable blowing agent. At page 17, lines 8-9 and page 20, lines 29-30, WO 99/16419 states that ammonium carbonate and camphor are suitable blowing agents. Therefore, Tarara's earliest priority date for the disclosure of including a volatile salt in the spray dried composition, as required by the pending claims, should be September 29, 1998.

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35 U.S.C. § 102(e)

Assuming the rejection should have been made under 35 U.S.C. § 102(e), this rejection is respectfully traversed. Enclosed is a declaration under 37 C.F.R. § 1.131 by Julie Straub and Howard Bernstein. In their declaration, Julie Straub and Howard Bernstein state that prior to September 29, 1997 they conceived of and reduced to practice compositions that are formed by spray drying a diagnostic agent with a surfactant and a blowing agent.

As noted in the copies of the laboratory notebook pages attached to the Declaration (Exhibit A), microparticles containing air as the diagnostic agent were formed by spray drying (see page 14). Air bubbles were encapsulated in synthetic polymer microparticles by a spray drying process. The feed stock to the spray drying apparatus included a blowing agent (ammonium acetate), a surfactant (lecithin), polymers (poly(ethylene glycol)-co-poly(lactide-co-glycolide) (75:25) and D,L-poly(lactide)), and a diagnostic agent (air). This composition was homogenized to form an emulsion, which was then spray dried using a small-scale lab spray dryer. The resulting microparticles were echogenic (see page 105, injection 7).


Tarara discloses using a spray drying feedstock which contains "a bioactive agent, surfactant, and a blowing agent" (abstract). Tarara defines "bioactive agent" as "a substance which is used in connection with an application that is therapeutic or diagnostic in nature." (col. 6, lines 30-32). As noted above, prior to September 29, 1997, applicants had conceived of and reduced to practice forming diagnostic particles using a spray drying feedstock which contains a bioactive agent, surfactant, and blowing agent. Therefore, Tarara is not available as prior art

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under 35 U.S.C. § 102(e). Assuming that a rejection under 35 U.S.C. § 102(a) could have been made in view of the corresponding PCT application, WO 99/16419, the enclosed Declaration would be effective to remove WO 99/16419 as prior art.

Allowance of claims 23-39, as amended, is respectfully solicited.

Respectfully submitted,



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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, January 22, 2004, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



Rivka D. Monheit

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